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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,880	10/22/2003	Nancy M. Lee	026837-000110US	8369

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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

MAIL DATE	DELIVERY MODE
01/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/690,880

Applicant(s)

LEE ET AL.

Examiner

Daniel M. Sullivan

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 December 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 27 December 2007. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 49,51-64,79,81-85,96,97.
Claim(s) withdrawn from consideration: 50,65-78,80,89-93 and 148.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/Daniel M Sullivan/
Primary Examiner
Art Unit: 1636

Continuation of 3. NOTE: Independent claim 49 has been amended such that it is now directed to a method for determination of colorectal cancer and colorectal polyps comprising comparing the quantity of biomarkers expressed in a sample from a subject to a normal control wherein a difference is indicative of a colorectal cancer and colorectal polyps. In the remarks filed with the 27 December amendment, Applicant contends that claim 49 has been amended to incorporate a portion of the preamble of claim 79 and the subject matter of claim 56 and, therefore, the subject matter incorporated into claim 49 was previously searched and does not introduce matter requiring an additional search.

This argument is not deemed persuasive. Previously examined claim 55 was directed to the method of claim 49 where the cDNA levels for the sample are compared to a cDNA level from an independently validated control and claim 79 was directed to a kit having an intended use of determining colorectal cancer and colorectal polyps. Neither of these claims require that a difference in the quantity of the identified biomarkers relative to a normal control is a definitive indicator of both colorectal cancer and colorectal polyps as recited in the amended claims. Although previously examined claim 57 recited that “an increase in at least one cDNA in the sample compared to cDNA levels from the normal control identifies the subject as a candidate for the management of colorectal cancer and colorectal polyps”. This is substantially different from the requirement that a difference in the expression of a panel of biomarkers is a definitive indicator of both colorectal cancer and colorectal polyps as presently claimed. Therefore, entry of the amendment would require a new search of the art and raises new issues for consideration under 35 USC § 112, first paragraph.

Continuation of 11. does NOT place the application in condition for allowance because: Claims 56-59 and 96-97 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Applicant's arguments and the opinions set forth in the declaration under 37 CFR §1.132 regarding the written description rejection are predicated upon entry of the claim amendment. As the amendment has not been entered, the arguments and opinions are moot with respect to the presently pending claims.

Claims 49, 51-64, 79, 81-88 and 96-97 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for reasons of record and extended to new claims 96-97. In response to the *prima facie* rejection and arguments of record, Applicant asserts that the claimed invention is enabled by the specification in view of the Declaration under 37 CFR §1.132 filed after final amendment. However, as the submission fails to provide a showing of good and sufficient reasons why the Declaration is necessary and was not earlier presented the showings will not be considered after final. See 37 CFR §1.116(e). It is noted, however, that it does not appear that the Declaration supports enablement for a method wherein any difference in the expression of the recited polynucleotides relative to any normal control is indicative of both colorectal cancer and polyps in the subject.